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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,821	02/27/2004	Revital Lifshitz-Liron	1662/62902	8234
26646	7590	02/22/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			DESAI, RITA J	
			ART UNIT	PAPER NUMBER

1625

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,821	LIFSHITZ-LIRON ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04;12/22/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims pending 1-12.

Priority

Applicants priority to provisional application filed 2/27/2003 has been noted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US

PreGrant 20040181086 102(e) date Kambiz Javdani et al

An expt. with acid mine water John Cattaneo 7/2000 .

Reeves US 4594466 1986.

Water treatment Susan Kegley et al

Applicants claim is drawn to purifying Zoledronic acid by first increasing the pH(making it basic till the acid dissolves) and then lowering the pH (making it acidic) till it precipitates out.

Then isolating the precipitate.

Determination of the scope and content of the prior art (MPEP §2141.01)

The prior art the US pregrant publication clearly teaches the crystallization of 2-nitro-4-methylsulfonylbenzoic acid.

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The school experiment also shows changing the pH of water to purify it.

The protein (amino acids) purification also teaches changing the pH to precipitate it out.

Recrystallization techniques is a age old method which requires dissolving and then prepipitating it out , but it is done by changing temperature .

Water treatment :- 2000 states

Session 5: How can we remove contaminants from a water supply?

Le Chatelier's principle and the effects of concentration, temperature, and pressure on the position of an equilibrium; common ion effect.

Exploration 5A: The Storyline

Exploration 5B: How can we drive an equilibrium reaction to one side?

Precipitation of copper iodate

Exploration 5C: Which precipitating reagent will remove the most contaminant?

Exploration 5D: How much precipitating reagent is required for effective water treatment?

Session 6: What procedures can you design to remove contaminants from a water supply?

Applying the principles of equilibrium and precipitation to remove contaminants from a water sample.

Exploration 6A: The Storyline

Exploration 6B: How can excess fluoride be removed from a water supply?

Exploration 6C: How can excess water hardness be removed from a water supply?

Exploration 6D: How can excess iron be removed from a water supply?

Session 7: What are acids and bases?

Definitions of acids and bases and their relative strengths; the pH scale; calculations involving strong and weak acids and bases; relationship of acid strength to structure and composition of the acid; thermodynamics of acid-base reactions.

Exploration 7A: The Storyline

Exploration 7B: How are acid and base strengths correlated to the extent of the acid-base reaction?

Exploration 7C: How can we best quantify acid and base concentrations?

Exploration 7D: How do you determine equilibrium concentrations of strong and weak acids and bases?

Exploration 7E: How is acid strength related to the structure and composition of the acid?

Session 8: What is the role of acids and bases in water treatment?

Effects of pH on solubility; neutralization reactions; analytical method for measuring pH.

Exploration 8A: The Storyline

Reeves US 4594466 teaches a method of separation of organic acids by phase separation making use of solubilities and pH.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The prior art specifically does not teach the technique with zoledronic acid.

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However there is a teaching with other acids (amino acids and also 2-nitro-4-methylsulfonylbenzoic acid.), Le Chateliers principle and also phase separations.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The state of the art is such that one would have found it obvious to purify by varying the pH. Water treatment plant use the same principle on a large scale to remove impurities. And also separation of acids is taught by the prior art.

Thus one of skill in the art would have found it obvious to purify the zoledronic acid by increasing and then lowering the pH.

Conclusion

The claims 1-12 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

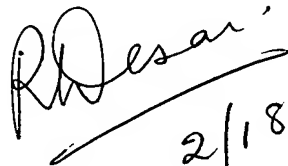
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
February 16, 2005 y


2/18/05